

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

Master Civil No. 01-cv-12257

MDL No. 1456

THIS DOCUMENT RELATES TO
CLASS 1 JOHNSON & JOHNSON

Judge Patti B. Saris

**THE JOHNSON & JOHNSON DEFENDANTS' STATEMENT REGARDING
POSITIONS TAKEN BY THE DEPARTMENT OF JUSTICE ON DR. HARTMAN'S
30% LIABILITY BENCHMARK**

The J&J Defendants hereby respond to the Court's July 12, 2010 inquiry concerning the Department of Justice's ("DOJ") position on Dr. Hartman's 30% liability benchmark.

I. The DOJ's Position

The J&J Defendants have not found any statement by the DOJ in the *Ven-A-Care* litigation record that explicitly endorses or disavows Dr. Hartman's 30% liability benchmark. However, consistent with Dr. Hartman's testimony and plaintiffs' admissions during the Track 1 trial in this case, the DOJ has repeatedly acknowledged that government policy makers understood that AWP's were higher than acquisition prices. The DOJ has also stated that the government expected AWP's to bear a reasonable relationship to acquisition prices. The DOJ's statements are thus consistent with the summary judgment record, including plaintiffs' admission that the government was aware of spreads in the range of 30% when it selected AWP as a reimbursement benchmark for Medicare. Additionally, when presented with the opportunity in this case to explicitly refute the 30% liability benchmark, the DOJ deliberately chose *not* to do so. While it did submit an amicus brief in connection with the BMS and AstraZeneca First

Circuit appeals in this case, it chose not to submit an amicus brief in connection with the appeal regarding the J&J Defendants, which squarely presented the question of whether the 30% liability threshold was appropriate.

The DOJ has described its position on four occasions.

First, in response to a question from the Court as to whether the Government believes there should be a spread threshold built in to the Court's liability and damages determinations, DOJ filed a position statement entitled "United States' Statement Regarding the Court's Prior Rulings." [Dkt. No. 5492]. DOJ emphasized in its statement that the 30% speed limit was not at issue in the *Ven-A-Care* cases, because those cases involved "drugs with megaspreads well above the spread thresholds identified in the [Track 1] AWP trial." DOJ then noted, in answer to the Court's question, that its litigation positions "were not premised on challenging *any* of the Court's rulings in other AWP matters in this multi-district litigation." *Id.* at 1, 2 (emphasis in original). Thus, although DOJ stopped short of explicitly endorsing Dr. Hartman's specific speed limit of 30%, it made it clear that it was not challenging the 30% speed limit either. Of course, because the "megaspreads" at issue in the *Ven-A-Care* cases substantially exceeded the 30% speed limit, the DOJ did not need to take a position with respect to that specific figure.

Second, in amicus briefs filed by the DOJ in the BMS and AstraZeneca appeals in the First Circuit, DOJ acknowledged that standard industry markups were built into the government's reimbursement formula and, as such, were not problematic (emphasis added):

HCFA elected to measure average wholesale price using industry publications based on the belief that they would reflect a reasonable estimate of actual drug prices in the marketplace--not a fabricated figure to be devised entirely at the manufacturers' discretion. *That expectation was fulfilled by most manufacturers,*

*whose list prices reflected only limited markups from their true prices.*¹

Consistent with the foregoing statement, the DOJ explicitly chose not to file an amicus brief in support of Class 1's appeal from the entry of judgment in favor of the J&J Defendants. This is significant as that appeal focused directly on whether 30% was an appropriate threshold for Class 1.

Third, Michael K. Loukes, the former Chief of the Health Care Fraud Unit for the U.S. Attorney's Office in Boston, stated on the record in the *United States v. MacKenzie*, CR-01-10350-DPW (D. Mass.), that Congress expected AWP to reflect a percentage markup over WAC. ("As a matter of fact, Your Honor, a historical fact . . . everybody got the spread between AWP and list price, the same 25 percent And the 25 percent, everyone gets that. *That's what Congress expected with AWP.*")² This statement is consistent with this plaintiffs' admission that "the market understood and expected a 20 to 25 percent formulaic markup from WAC to AWP." *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d, 20, 91 (D. Mass. 2007).

Fourth, in the three *Ven-A-Care* cases in which the government has intervened, the DOJ has affirmatively disclaimed damages for spreads of 25 percent. *See, e.g.*, Exp. Rpt of Mark g. Duggan, Ph.D., submitted in *United States ex rel. Ven-A-Care of the Florida Keys, Inc.*

¹ DOJ's amicus brief in the *AstraZeneca* appeal is annexed to the accompanying Declaration of Adeel A. Mangi as Exhibit 1. The block quote appears at page 16 of DOJ's brief.

² Mr. Loukes' statement is included as Exhibits 8 and 10 respectively to the November 23, 2009 Declarations of Andrew D. Schau in Support of the Johnson & Johnson Defendants' Motions for Summary Judgment Against Class 1 Residents of the Commonwealth of Massachusetts and Class 1 Residents of the District of Columbia and Residents of States Other than the Commonwealth of Massachusetts.

v. Abbott Labs., Inc., Case No. 07-CV-011618-PBS, Dkt. No. 6626-3, at 8-9. DOJ has noted that this 25% carve out for damages is analogous to the Hartman “speed limit.”

In sum, the DOJ has sued manufacturers whose spreads it characterizes as “megaspreads,” but it has not sued manufacturers whose spreads adhered to the standard industry markup. Indeed, the DOJ has acknowledged that the standard markup is consistent with the government’s expectations.

II. This Court May Consider DOJ’s Position in Deciding Johnson & Johnson’s Motions for Summary Judgment

Not surprisingly, plaintiffs ask the Court to disregard DOJ’s position that the standard markup was understood by Congress and HCFA when they set the reimbursement rate. Plaintiffs argue that the Court may not consider the DOJ’s position because it is not *evidence*. See Pl.’s Memo. at 3. Plaintiffs cite cases which say that evidence which is not part of a summary judgment record should not be considered.

Respectfully, plaintiffs’ have addressed the wrong question. The J&J Defendants do not claim that the DOJ’s position statements in this Court are *evidence*, but that does not mean the statements cannot be considered. The DOJ’s statements should be considered because they set forth the government’s official position on what Congress and HCFA understood and expected when AWP was selected as the reimbursement benchmark for Medicare Part B. The Court can and should take note of the government’s *position*, even if it is not evidence, because the DOJ’s statements make it clear that the government *does not dispute* the factual bases for the Court’s liability analysis. The DOJ’s statements are consistent with Dr. Hartman’s testimony, which, of course, is evidence. The J&J Defendants rely on Dr. Hartman’s testimony in their motions for summary judgment. The fact that the DOJ does not dispute this evidence is an important factor to consider in deciding whether to grant the J&J Defendants’ motions.

III. The Court Should Disregard Plaintiff's Merits Arguments

In Point III of their memorandum, plaintiffs repeat arguments made previously in their opposition to the J&J Defendants' summary judgment motions. The Court did not invite additional submissions on the merits, so plaintiffs' inclusion of these arguments in their memorandum is inappropriate. In any event, the J&J Defendants have already addressed each of plaintiffs' arguments in the reply memoranda in support of their summary judgment motions. The Court is respectfully referred to those memoranda.

Dated: July 20, 2010

Respectfully submitted,

/s/ Adeel Mangi

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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

I, Adeel A. Mangi , hereby certify that I am one of the attorneys for the J&J Defendants and that, on July 20, 2010, I caused a copy of the foregoing to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Adeel A. Mangi